



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

Exactech, Incorporated
Mr. Graham L. Cuthbert
Regulatory Affairs Specialist II
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K101909

Trade/Device Name: Exactech® Equinox® Platform Fracture Stem
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS
Dated: July 7, 2010
Received: July 8, 2010

Dear Mr. Cuthbert:

This letter corrects our substantially equivalent letter of August 2, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Exactech® Equinox® Platform Fracture Stem
Special 510(k) – Indications for Use**

510(k) Number:

K101909

AUG 09 2010

Device Name: Exactech® Equinox® Platform Fracture Stem

INDICATIONS FOR USE:

The Equinox Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi- arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

| P | L | F | Indications |
|---|---|---|--|
| ✓ | ✓ | | Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems |
| ✓ | ✓ | | Congenital abnormalities in the skeletally mature |
| ✓ | | | Primary and secondary necrosis of the humeral head. |
| ✓ | | ✓ | Humeral head fracture with displacement of the tuberosities |
| ✓ | ✓ | | Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable |
| ✓ | ✓ | | Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved) |
| | | ✓ | Displaced three-part and four-part upper humeral fractures |
| | ✓ | | Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases) |
| | ✓ | | Revision of failed previous reconstructions when distal anchorage is required |
| ✓ | ✓ | | To restore mobility from previous procedures (e.g. previous fusion) |

The Equinox Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinox Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinox Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinox Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinox Platform Fracture Stem is indicated for cemented use only.

[Signature]
(Division Sign-off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

K101909

Exactech® Equinox® Platform Fracture Stem
Special 510(k) – Indications for Use

Prescription Use X
(Part 21 CFR 801 Subpart D)

and/or

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonathan J. for mxm
(Division Sign/Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101909

**Exactech® Equinox® Platform Fracture Stem
Special 510(k) – Summary of Safety and Effectiveness**

I. Company: Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

Contact Person: Graham L. Cuthbert, Regulatory Affairs Specialist II

Date: July 6th 2010

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II. Proprietary Name: Exactech Equinox Platform Fracture Stems

Common Name: Fracture Shoulder Prosthesis

Classification Name:

- Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650, Class II, Product Code KWT)
- Prosthesis, Shoulder, Semi-constrained, metal/polymer cemented (21 CFR 888.3660, Class II, Product Code KWS)

III. Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

| <u>510(k) Number</u> | <u>Trade of Proprietary Model Name</u> | <u>Manufacturer</u> |
|----------------------|--|---------------------|
| K092900 | Equinox Platform Fracture Stem | Exactech, Inc |

IV. Device Description:

The Exactech Equinox Platform Fracture Stem is a cemented humeral stem designed for use with the Equinox primary shoulder components and the Equinox reverse shoulder components. The Equinox Platform Fracture Stem is intended to be used in cemented applications for repair of acute fracture of the proximal humerus.

The proposed and predicate (K092900) fracture stems have identical design features. However, the proposed stems will be made from forged titanium alloy (per ASTM F136 and ASTM F620), as opposed to the wrought titanium alloy (ASTM F1472) used in the predicate stems.

V. Intended Use of the Device

The Equinox Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment. Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

| P | L | F | Indications |
|---|---|---|---|
| √ | √ | | Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems |

**Exactech® Equinox® Platform Fracture Stem
Special 510(k) – Summary of Safety and Effectiveness**

| | | | |
|---|---|---|--|
| √ | √ | | Congenital abnormalities in the skeletally mature |
| √ | | | Primary and secondary necrosis of the humeral head. |
| √ | | √ | Humeral head fracture with displacement of the tuberosities |
| √ | √ | | Pathologies where arthodesis or resectional arthroplasty of the humeral head are not acceptable |
| √ | √ | | Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved) |
| | | √ | Displaced three-part and four-part upper humeral fractures |
| | √ | | Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases) |
| | √ | | Revision of failed previous reconstructions when distal anchorage is required |
| √ | √ | | To restore mobility from previous procedures (e.g. previous fusion) |

The Equinox Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinox Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinox Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinox Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinox Platform Fracture Stem is indicated for cemented use only.

**VI. Rationale for Substantial Equivalence
Equinox Fixed Angle Replicator Plate:**

- **Intended Use / Indications for Use.** The Equinox Platform Fracture Stem and the predicate device are intended for use in total shoulder joint replacement and have identical indications for use.
- **Materials.** The Equinox Platform Fracture Stem and the predicate device are composed of equivalent biocompatible materials conforming to recognized industry standards for permanent implants.
- **Design Features.** The Equinox Platform Fracture Stem and the predicate device have identical design features.
- **Dimensions.** The Equinox Platform Fracture Stem and the predicate device have identical geometry.
- **Packaging and Sterilization.** The Equinox Platform Fracture Stem and the predicate device are packaged and sterilized using identical materials and processes.

**Exactech® Equinoxe® Platform Fracture Stem
Special 510(k) – Summary of Safety and Effectiveness**

- **Device Shelf Life.** The Equinoxe Platform Fracture Stem and the predicate device have the identical shelf life.

VII. Summary of Non-Clinical Performance Data

Mechanical tests and Engineering evaluations were conducted to demonstrate substantial equivalence of the proposed device to the predicate Equinoxe Platform Fracture Stem

- A dynamic compression test was conducted. All constructs met the criteria without failure.
- An engineering evaluation determined under worst case conditions that the proposed device is sufficient to sustain clinically relevant loads during its expected life.

The results demonstrate that the proposed device is as substantially equivalent to the predicate device.